UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, Plaintiff, v. RHODY DAIRY, L.L.C., a limited liability company, and JAY L. DE JONG, an individual, Defendants.	CASE NO. C11-0065-RSM ORDER ON SUMMARY JUDGMENT AND REQUEST FOR INJUNCTION

I. INTRODUCTION

This matter comes before the Court on Motions for Summary Judgment brought by Plaintiff United States of America ("Government") and Defendants Rhody Dairy L.L.C. and Jay L. De Jong ("Defendants") (Dkt. 11, 18), and on the Government's request for injunctive relief pursuant to 21 U.S.C. § 332(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Dkt. 11. The Government alleges that Defendants have violated several provisions of the FDCA. Defendants have denied that their conduct violates the FDCA.

II. BACKGROUND

This action arises out of several inspections the Food and Drug Administration ("FDA") conducted of Defendants' dairy farm. Defendants are in the business of selling cow's milk and selling cows for beef. The FDA conducted an inspection of Defendants' farm in 2004, and twice in 2010. During these inspections, the FDA alleges that it observed a number of violations. Specifically, the Government now contends that Defendants have violated §§ 331(a), 331(k), and 331(u). Accordingly, the Government seeks a statutory injunction under § 332(a) permanently enjoining Defendants from violating the above provisions of the FDCA and to bring themselves into compliance to the satisfaction of the FDA. Defendants counter that they have not violated any provisions of the FDCA because the Government has misconstrued the statutory language, the alleged misconduct did not result in an actual violation, and there is no record keeping requirement imposed by the statute. Defendants also contend that the injunction is improper.

III. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. FRCP 56; *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). The Court must draw all reasonable inferences in favor of the non-moving party. See *F.D.I.C. v. O'Melveny & Meyers*, 969 F.2d 744, 747 (9th Cir. 1992), *rev'd on other grounds*, 512 U.S. 79 (1994). In ruling on summary judgment, a court does not weigh evidence to determine the truth of the matter, but "only determine[s] whether there is a genuine issue for trial." *Crane v. Conoco, Inc.*, 41 F.3d 547, 549 (9th Cir. 1994) (citing O'Melveny & Meyers, 969 F.2d at 747). Material facts are those which might affect the outcome of the suit under governing law. *Anderson*, 477 U.S. at 248.

IV. ARGUMENT

A. 21 U.S.C. § 331(a)

The Government alleges that Defendants have violated 21 U.S.C. § 331(a). Section 331(a) of the FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated" within the meaning of § 342(a)(4). The elements for establishing a violation of this provision are: (1) the product at issue is food; (2) there is an interstate commerce nexus; and (3) the food is adulterated. *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 42 (E.D.N.Y. 2001), *aff'd in relevant part*, 56 Fed. App'x 542 (2d Cir. 2003).

Defendants contend that the Government has not proven that a specific individual animal was improperly administered drugs and then sold for slaughter, and thus cannot prove that adulterated food was sold. Defendants' contention is without merit. The law is clear that § 342(a)(4) requires that the Government need only show a "reasonable possibility" that conditions under which the food is "prepared, packed, or held" may render the food injurious to health. *See id.* at 44.

Defendants further assert that their administration of animal drugs does not constitute "insanitary conditions" under § 342(a)(4) and that § 342(a)(4) does not impose a recordkeeping requirement on dairy farms. Under § 342(a)(4), "insanitary conditions" is construed to "include a lack of adequate controls concerning treatment of food-producing animals with drugs." *See* FDA, Proper Drug Use and Residue Avoidance by Non-Veterinarians, Compliance Policy Guide ("CPG") § 615.200, available at http://www.fda.gov/ICECI/Compliance Manuals/CompliancePolicyGuidanceManual/ucm074660.htm. The Government contends that by

not keeping adequate records of their administration of drugs to cows, Rhody Dairy operates under "insanitary" conditions within the meaning of § 342(a)(4). Yet, according to Defendants, the FDA cannot impose such an obligation in the absence of more specific regulatory requirements.

Regardless of whether the language specifically requires the dairy farm to maintain records of the its drug administration, § 342(a)(4) is clear in that its purpose is to prevent conditions that may render food harmful to the health of consumers. Furthermore, the administration of drugs to animals without adequate control measures can doubtlessly lead to conditions which could produce adulterated food. *See* 58 Fed. Reg. 39,218 (July 22, 1992). Therefore, Defendants' administration of animal drugs constitutes "insanitary conditions" under § 342(a)(4).

Finally, Defendants contend that genuine issues of fact exist regarding the adequacy of their recordkeeping. However, the adequacy of Defendants recordkeeping is not an issue of fact, but rather a legal conclusion. The FDA has documented *facts* regarding Defendants operations. These facts reveal a number of inadequacies that were apparent over the course of three visits. The observations included failure to maintain documentation of the treatment history, the disease conditions treated, the dosages used, the route of administration, the person administering the drug, the pre-slaughter withdrawal times, and an inventory system for accounting for the drugs administered to animals, among other inadequacies. Dkt. 11 at 4-7.

Against this record, Defendants assert that they are aware of the necessary data concerning the administration of drugs because they employ "a standard procedure for how each drug is administered." Dkt. 26 at 11. This standard procedure includes use of a chalkboard where dates are recorded, a sheet from the veterinarian that lists withdrawal times for drugs

administered, and placement of an ear tag on the animal with the cow number, drug administered, and date of administration. *Id.* However, Defendants' conclusion that it engages in adequate record keeping will not suffice for this Court to disregard Defendants' failure to produce satisfactory records during three past inspections. Rather, this Court must conclude that Defendants lack adequate controls for the administration of animal drugs, and that they are not in conformance with § 331(a).

B. 21 U.S.C. § 331(k)

Section 331(k) of the FDCA prohibits the performance of any act with respect to a drug that may result in the drug being adulterated while held for sale after shipment in interstate commerce. The elements of a violation of § 331(k) are that (1) the relevant product is a drug or drug component, (2) defendants received the drug or drug component after shipment in interstate commerce, and (3) defendants have adulterated or caused the adulteration of the drug component. *United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d. at 42 (discussing § 331(k) in the context of food adulteration).

1. "Held for sale" language

Defendants set forth several grounds on which they rest their theory that they have not violated § 331(k). First, Defendants contend that § 331(k) is inapplicable because they have not "held for sale" any drugs within the meaning of the statute. Accordingly, Defendants believe that the Government's interpretation of the phrase, "held for sale" is overly expansive.

The Government argues that the "held for sale" requirement is satisfied if the product can be shown to have been used for any purpose other than for the defendant's personal consumption. This argument is grounded on the notion that the FDCA is to be interpreted in such a way so as to protect the public health and is to be liberally construed. *See United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *United States v. Articles of*

Drug Containing Diethylstilbestrol, 528 F. Supp. 202, 205 (D. Neb. 1981). Furthermore, cases addressing the substantive issue of what constitutes being "held for sale" are consistent with a broader interpretation of the statute. For example, several cases have held that drugs and devices used in the treatment of patients are "held for sale" by doctors as part of the distribution process. *See United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981); *United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2nd Cir. 1975); *United States v. Article of Device . . . Cameron Spitler*, 261 F. Supp. 243, 246 (D. Neb. 1966).

Defendants, by contrast, rely on *United States v. Geborde* for the proposition that "held for sale" has a narrower definition than simply meaning "other than for personal consumption." 278 F.3d 926 (9th Cir. 2002). In *Geborde*, the court held that a criminal defendant who gave away illegal drugs did not hold those drugs for sale within the meaning of § 331(k). However, in distinguishing *Geborde*, the court noted that the defendant distributed homemade items to friends free of charge, and therefore concluded that the setting was noncommercial. *Id*. at 931. Yet unlike *Geborde*, the products in question in the present case are distributed in a commercial setting. As such, *Geborde* says nothing that calls into doubt case law that supports a broad definition of the term "held for sale." In fact, *Geborde* goes on to explain that defendants in previous cases have been held to violate § 331(k) where the cases "clearly involve commercial transactions, commercial actors, and commercial products." *Id*. As such, the Defendants have held drugs for sale within the meaning of § 331(k).

2. "Adulterated"

As discussed supra, a violation under § 331(k) also requires the drugs in question to be "adulterated." According to § 351(a)(5), a drug is adulterated "if it is a new animal drug which is unsafe within the meaning of § 360b." Under § 360b(a)(4)(A), an animal drug is unsafe if it is used in a manner that differs from that specified by the drug's approved labeling. Extra-label use

is permitted in limited circumstances, including (1) a prescription by a licensed veterinarian in the context of a valid veterinarian-client-patient relationship; (2) the drug is not prohibited from extra-label use under 21 C.F.R. § 530.41; and (3) the use does not result in illegal drug residues in the edible animal tissues. *See* 21 U.S.C. 360(a)(1), (4); 21 C.F.R. Part 530.

Defendants do not qualify for any of the above noted exceptions. Defendants have not presented this Court with evidence of prescription records that indicate that they had valid prescriptions for the extra-label uses. Despite Defendants' contention that their veterinarian "orally okayed" the extra-label use, evidence of actual diagnoses and Defendants' compliance with the veterinarian's instructions regarding the extra-label use is lacking.

Defendants have further argued that the violation regarding their use of tetracycline was only technical because although the tetracycline they used lacked instructions on treating lactating cows, tetracycline drugs produced by other manufacturers are indicated for use on lactating cows. However, as the Government sets forth, withdrawal times differ between lactating and non-lactating cows, and therefore instructions may differ. Dkt. 24 at 14. Furthermore, Defendants cannot be exempted from their obligation to follow the relevant regulations because their violation was merely technical. The Government has demonstrated sufficient evidence of several violations arising from the use of drugs that differs from their approved labeling.

C. 21 U.S.C. § 331(u)

Section 331(u) prohibits the extra-label use of new animal drugs by failing to comply with the requirements set forth in § 360b(a)(4)(A). The safety of animal drugs under § 360b(a)(4)(A) is discussed *supra*. *See* IV(B)(2) of this Order (discussing § 360b(a)(4)(A) and Defendants extra-label use of new animal drugs in the statute). Accordingly, this Court has

already concluded that Defendants have not complied with these requirements, and have thus violated § 331(u).

D. Claim Abandonment

Defendants contend that the Government has abandoned its residue violation claims by deciding not to pursue them on summary judgment. Pursuant to a status conference held before this Court (Dkt. 8), the parties agreed that if the Government proceeds on the general observations obtained from the site inspections, the parties would forego discovery. However, if the Government seeks to investigate drug residue in specific animals, the parties would then engage in discovery. This understanding between the parties does not support Defendants' contention that the Government has waived or abandoned its claims that would require residue testing. The Government has specifically reserved its right to pursue those claims, and has not demonstrated any intention of abandoning them. Dkt. #11 at 2, n. 1. Moreover, Rule 56(a) states that "[a] party may move for summary judgment, identifying each claim or defense – or the part of each claim or defense – on which summary judgment is sought." Fed. R. Civ. P. 56(a). As such, there is no requirement that a moving party seek summary judgment on all claims or lose the right to pursue outstanding claims.

Defendants are concerned that they have not had the benefit of discovery with respect to the residue violation claims. However, pursuant to the parties' agreement, if the Government decides to pursue the residue violation claims in the future, then the parties will commence the discovery process. As such, Defendants' concerns are unfounded.

E. Injunction

The Government seeks to enjoin violations of § 331 pursuant to § 332(a). Statutory injunctions issued under section 332(a) employ a different standard than that which is applicable to private litigants in equity, and as such the standard requiring a showing of probable success on

the merits and the possibility of irreparable injury is inapplicable. *United States v. City and County of San Francisco*, 310 U.S. 16, 30-31 (1940); *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1177 (9th Cir. 2002). Rather than requiring a showing of probable success on the merits and possibility of irreparable injury, a party seeking a statutory injunction must show "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953).

In this case, the Government has made a sufficient showing to support the issuance of a statutory injunction. Defendants have demonstrated a prolonged resistance to conformance with the regulations imposed by the FDA and have not taken measures to achieve compliance, despite several notices provided by the Government subsequent to the inspections beginning in 2004. Furthermore, there is scant indication that Defendants' have taken measures to bring themselves into lasting compliance so as to cure themselves of the violations. Therefore, the Government has made a sufficient showing that there is "some cognizable danger of a recurrent violation," and the Government's request for an injunction pursuant to § 332(a) is granted. *Id*.

F. Motion to Strike

Defendants' Motion to Strike is denied.

V. CONCLUSION AND INJUNCTION

Having reviewed the relevant pleadings, the declarations and exhibits attached thereto, and the remainder of the record, the Court hereby finds and ORDERS:

(1) Defendants' Motion for Summary Judgment (Dkt. 18) is DENIED.

(2) Government's Motion for Summary Judgment (Dkt. 11) is GRANTED.

(3) This action is DISMISSED. The Clerk is directed to close this case.

(4) Government's request for injunctive relief is GRANTED and the Court adopts the following:

I. Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them who have received notice of this Order, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a), and the inherent equity authority of this Court, from directly or indirectly introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, any article of food, within the meaning of 21 U.S.C. § 321(f), excluding milk, and administering to animals any drug, including, but not limited to any new animal drug, as defined in 21 U.S.C. § 321(v), while such drugs are held for sale after shipment in interstate commerce, unless and until:

A. Defendants have established and implemented a system that ensures that each of the animals that they acquire, purchase, hold, transport, sell, consign, or lease is individually and permanently identified by tag number;

B. Defendants have established and implemented a written record-keeping system that prevents them from selling, consigning, leasing, or distributing any animals whose edible tissue contains new animal drugs in amounts above the levels permitted by law. This system shall include, but not necessarily be limited to, keeping written records on every animal to which Defendants administer drugs. These records shall include, at a minimum: (1) the identity of each animal that Defendants medicate; (2) the date of each administration of each medication to each animal; (3) the identity of each drug administered; (4) the dosage of each drug used; (5) the route of administration of each drug used; (6) the lawful written order of a licensed veterinarian within the context of a

veterinarian-client-patient relationship for each drug used, if applicable; (7) the name of the person administering each drug; (8) the proper withdrawal period for each drug administered; (9) the date such withdrawal period will terminate for each drug administered; (10) the date each medicated animal is shipped for slaughter or leaves Defendants' control; and (11) the name and address of the purchaser, receiver, lessee, or consignee of each medicated animal that is shipped for slaughter or leaves Defendants' control;

C. Defendants have established and implemented a system that ensures that their use of new animal drugs conforms to the uses approved by the United States Food and Drug Administration ("FDA") and as set forth in the drugs' approved labeling or, for new animal drugs used in an extra-label manner, to the lawful written orders of a licensed veterinarian in accordance with 21 U.S.C. § 360b(a)(4)(A), so long as those orders do not result in illegal residues. This system shall include, but not necessarily be limited to, measures to ensure that the following will not occur: (1) administration of drugs in excess of the approved dosage, unless the extra-label use is in accordance with the lawful written orders of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530; (2) sale or delivery for slaughter of medicated animals before the expiration of the relevant withdrawal period; (3) use in Defendants' animals of drugs not approved for use in that species or not approved for the disease or other condition for which the animal is being treated, unless, for new animal drugs, such extra-label use is in accordance with the lawful written orders of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21

C.F.R.Part 530; and (4) administration of drugs by a non-approved route, unless, for new animal drugs, such extra-label use is in accordance with the lawful written orders of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530;

D. Defendants have established and implemented a drug inventory and accountability system that prevents them from selling, consigning, leasing, or delivering any animals with illegal new animal drug residues in their edible tissues. This system shall include a written record for each drug that Defendants purchase or receive for use in medicating any of their animals. These records shall include, but not necessarily be limited to: (1) the name of the drug; (2) the date of purchase or receipt of the drug; (3) the quantity, strength, and form of the drug purchased or received; (4) the expiration date of the drug purchased or received; (5) the name and address of the supplier or seller of the drug; (6) the date each drug is administered; and (7) the amount and method of each administration of each drug. In addition, the inventory and accountability system shall include periodic checks of inventory and records, no less frequently than once every fourteen (14) days, to ensure that the records accurately document the drugs currently on hand and the disposition of all drugs purchased or received, including whether the drugs have been administered;

E. Defendants have established and implemented a quarantine or segregation system that ensures ready distinction between medicated and un-medicated animals and that prevents Defendants from selling, consigning, leasing, and delivering for slaughter for use as food any animals with illegal new animal drug residues in their edible tissues;

F. Defendants have established and implemented a system that ensures that each animal that has been medicated is not directly or indirectly sold, consigned, leased, or delivered for immediate or ultimate slaughter until the withdrawal period (specified in the drug's approved labeling or, for new animal drugs used in an extra-label manner, in the lawful written orders of a licensed veterinarian made in accordance with 21 U.S.C. § 360b(a)(4)(A)) for each drug used on such animal, has expired. This system shall also ensure that each purchaser, receiver, lessee, or consignee receives, prior to accepting any animal, a written statement from Defendants certifying that any animal that has been medicated has also been withdrawn from drugs for the appropriate time period or that the animal has not been medicated. This written statement must also include the date(s) on which the animal was medicated, each drug with which the animal was treated, the required withdrawal period for each drug, and the date(s) on which the withdrawal period(s) expired. Defendants shall, prior to selling, leasing, or otherwise transferring any animal, obtain the signature of the purchaser, receiver, lessee, or consignee documenting date of receipt of the statement from Defendants. Defendants shall keep, as part of their records, a copy of the signed written statement described in this paragraph;

G. Defendants have established and implemented a system that identifies the source of each animal that they purchase or otherwise receive and ensures that Defendants obtain the following document(s) prior to taking possession of any animal:

1. A signed written statement from the seller, transferor, or auction house certifying that the animal does not have illegal drug residues; or

2. A signed written statement from the seller, transferor, or auction house identifying the name of each drug administered to the animal, the date each

such drug was administered to the animal, and the date on which the withdrawal period will expire. Defendants shall keep, as part of their records, a copy of the document(s) described in this paragraph;

H. Defendants have reported to FDA in writing the steps they have taken to comply with paragraphs I(A)–(G);

I. FDA has inspected Defendants' operations, including all records relating to the medication, purchase, sale, consignment, and distribution of food-producing animals;

J. Defendants have paid for the costs of the inspections; and

K. FDA has notified Defendants in writing that they appear to be in compliance with the requirements of the Act, its implementing regulations, and paragraphs I(A)–(H) and (J) of this Order.

II. Prior to obtaining written notification of compliance from FDA as specified in paragraph I(K), Defendants may administer drugs as prescribed to an ill, food-producing animal that they own, but only after the animal has been examined by a licensed veterinarian and that veterinarian has diagnosed and prescribed the particular drug for that animal. Defendants shall submit copies of the veterinarian's diagnosis, prescription, and receipts for treatment or the equivalent to FDA within ten (10) calendar days after treatment.

III. Defendants shall maintain all records described in paragraph I for each animal for a period of at least two (2) years after the date that Defendants sell, consign, deliver, or lease the animal. These records shall be made available immediately to FDA upon its request for purposes of inspection and copying.

IV. Within fifteen (15) calendar days after the entry of this Order, Defendants shall provide a copy of the Order, by personal service or certified mail (return receipt requested) to each and all of Defendants' officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, and all persons to whom Defendants have sold, consigned, or delivered any cattle or calves for slaughter within one (1) year preceding the date of entry of the Order. Defendants shall also post a copy of this Order in an employee common area and explain the terms of the Order to each employee. Within twenty (20) calendar days after the entry of this Order, Defendants shall provide an affidavit of compliance from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Order.

V. After entry of the Order, Defendants shall, within five (5) calendar days of employment of any new employee at Defendants' operations: (a) provide a copy of the Order, by personal service or by certified mail (return receipt requested) to all such employees; and (b) explain the terms of the Order.

VI. After Defendants receive written notification from FDA as specified in paragraph I(K), Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing and delivering for introduction into interstate commerce any article of food, within the meaning of 21 U.S.C. § 321(f), that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) or 342(a)(4);

B. Administering to any food-producing animal any article of drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), unless such administration is in a manner that strictly conforms to such drug's labeled indications and conditions for use or, for new animal drugs used in an extra-label manner, such administration is by or on the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and in compliance with 21 U.S.C. § 360b(a)(4)(A) and 21 C.F.R. Part 530;

C. Doing any act with respect to any article of drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), if such act is done while such drug is held for sale after shipment in interstate commerce and results in such drug being adulterated within the meaning of 21 U.S.C. § 351(a)(5); and

D. Failing to implement and continuously maintain the requirements of this Order.

VII. Duly authorized representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations, including any new locations, and any facility or location at which Defendants hold or store drugs used to treat animals, including food-producing animals and, without prior notice, to take any other measures FDA deems necessary to monitor and ensure continuing compliance with the terms of this Order. Such inspections may, at FDA's discretion, include the taking of photographs, video recordings, and samples, and the examination and copying of all records that relate to the drug administration and the holding, delivery, sale, consignment, or distribution of food-producing animals at any facility or location Defendants operate, manage, or control. Such inspections shall be permitted upon presenting a copy of this Order and appropriate credentials. The inspection

authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

VIII. Upon FDA's request, Defendants shall promptly provide any information and records to FDA regarding the sale, consignment, delivery, or medication of any animals.

IX. Defendants shall pay the costs of FDA's supervision, inspections, examinations, reviews, and analyses conducted pursuant to this Order at the standard rates prevailing at the time that the activities are accomplished. As of the date of entry of this Order, these rates are: $87.57 per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work; $104.96 per hour and fraction thereof per representative for laboratory and analytical work; 50 cents per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent, for the areas in which the inspections are performed, per representative for subsistence expenses where necessary. In the event that the standard rates generally applicable to the FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

X. If any Defendant violates this Order and is found in civil or criminal contempt thereof, that Defendant shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs relating to such contempt proceedings.

XI. If, based on the results of any inspection or analysis conducted after the inspection described in paragraph I(I) or any other information, FDA finds that any Defendant is not in compliance with the Act, its implementing regulations, or the requirements of this Order, FDA

may, as and when it deems necessary, notify Defendants in writing of the non-compliance and require that Defendants immediately take one or more of the following actions:

A. Cease selling or delivering, and causing to be sold or delivered, any article of food within the meaning of 21 U.S.C. 321(f);

B. Cease medicating animals in a manner inconsistent with the drugs' labeled indications and conditions for use or the lawful written orders of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and FDA's regulations set forth in 21 C.F.R. Part 530; and/or

C. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Order, the Act, and FDA regulations. Upon receipt of such notification, Defendants shall immediately and fully comply with the terms of the notice. Any cessation of operations or other action ordered by FDA as described above shall continue until receipt by Defendants of written notification from FDA that Defendants appear to be in compliance with the terms of this Order, the Act, and all applicable regulations.

XII. Defendants shall notify FDA at least thirty (30) calendar days before any change in ownership, name, or character of the business that occurs after the entry of this Order, such as reorganization, relocation, assignment, or sale of the business that may affect compliance obligations arising out of this Order. Defendants shall provide a copy of this Order to any prospective successor or assignee at least thirty (30) calendar days prior to such sale or change of business, and shall furnish to FDA an affidavit of compliance with this paragraph within fifteen (15) calendar days of such sale or change of business.

XIII. Defendants shall address all notifications, correspondence, and communications to FDA under this Order to the Director, FDA Seattle District Office, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

XIV. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final and, if challenged, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

XV. If any Defendant fails to comply with the provisions of this Order, that Defendant shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day that the Defendant fails to comply with this Order and an additional five thousand dollars ($5,000.00) for each animal that the Defendant sells or delivers for sale in violation of this Order. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States of America to seek, and the Court to impose, additional criminal or civil contempt penalties based on conduct that may also be the basis for the payment of liquidated damages.

XVI. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary and appropriate.

Dated this 14th day of July 2011.

RICARDO S. MARTINEZ
UNITED STATES DISTRICT JUDGE